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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORPORATION and MSP SINGAPORE COMPANY LLC,	§	
Plaintiffs/Counterclaim Defendants,	§	
	§	Civil Action No. 07-cv-01334 (JLL)
v.	§	
	§	JURY TRIAL DEMANDED
GLENMARK PHARMACEUTICALS, INC., USA, and GLENMARK PHARMACEUTICALS, LTD.,	§	
Defendants/Counterclaim Plaintiffs.	§	

GLENMARK PHARMACEUTICALS, LTD.'S,
FIRST AMENDED ANSWER AND COUNTERCLAIMS

Defendant / Counterclaim Plaintiff Glenmark Pharmaceuticals, Ltd. ("Glenmark Ltd."), by and through its attorneys, hereby amends its corrected answer to the Complaint (the "Complaint") of Plaintiffs / Counterclaim Defendants Schering Corporation ("Schering") and MSP Singapore Company LLC ("MSP") (collectively, the "Plaintiffs"), as follows:

THE PARTIES

1. Glenmark Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 1 of the Complaint, and therefore denies the same.

2. Glenmark Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 2 of the Complaint, and therefore denies the same.

3. Glenmark Ltd. admits that Glenmark Pharmaceuticals Inc., USA ("Glenmark USA") is a Delaware corporation wholly-owned by Glenmark Ltd., with a place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Glenmark Ltd. denies the remaining allegations set forth in paragraph 3 of the Complaint.

4. Admitted.

JURISDICTION AND VENUE

5. Admitted.

6. Admitted.

7. Admitted.

8. Glenmark Ltd. admits that this Court has personal jurisdiction over it by virtue of its (1) presence in New Jersey; and (2) contacts with New Jersey. Glenmark Ltd. denies the remaining allegations set forth in paragraph 8 of the Complaint.

9. Admitted.

GENERAL ALLEGATIONS

10. Glenmark Ltd. admits that Exhibit A to the Complaint purports to be a true and correct copy of U.S. Patent No. RE 37,721 ("the '721 patent"). Glenmark Ltd. is

without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in paragraph 10 of the Complaint, and therefore denies the same.

11. Glenmark Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 11 of the Complaint, and therefore denies the same.

12. Glenmark Ltd. is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in paragraph 12 of the Complaint, and therefore denies the same.

13. Glenmark Ltd. admits that the '721 patent is in the list of Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") and that the Orange Book is maintained by the U.S. Food and Drug Administration ("FDA"). Glenmark admits that 21 U.S.C. §355(b)(1) reads in part:

> The applicant shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. . . . Upon approval of the application, the Secretary shall publish information submitted under the two proceeding sentences.

Glenmark Ltd. denies any remaining allegations set forth in paragraph 13 of the Complaint.

14. Glenmark Ltd. admits that it has filed an Abbreviated New Drug Application ("ANDA") No. 78-560 with the FDA seeking approval to market an ezetimibe

product. Glenmark Ltd. denies any remaining allegation set forth in paragraph 14 of the Complaint.

15. Glenmark Ltd. admits that ANDA No. 78-560 includes a Paragraph IV certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), alleging that the '721 patent is invalid or will not be infringed by the manufacture, use, or sale of Glenmark Ltd.'s ezetimibe product. Glenmark Ltd. denies any remaining allegation set forth in paragraph 15 of the Complaint.

16. On information and belief, admitted.

17. Glenmark Ltd. admits that 35 U.S.C. § 271 (e)(2)(A) states the following:

> (e)(1) It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.
>
> (2) It shall be an act of infringement to submit -
>
> (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent, or ….

Paragraph 17 of the Complaint states legal conclusions to which no further response is required. To the extent a further response is required, Glenmark Ltd. denies any and all allegations set forth in paragraph 17 of the Complaint.

18. Glenmark Ltd. admits that if ANDA No. 78-560 is approved by the FDA, that Glenmark USA may market and distribute an ezetimibe product in the United States. Glenmark Ltd. denies the remaining allegations set forth in paragraph 18 of the Complaint.

19. Denied.

20. Denied.

21. Denied.

CLAIM

22. Glenmark Ltd. incorporates its responses to paragraphs 1 through 21 above, as if fully set forth herein.

23. Denied.

24. Denied.

25. Denied.

26. Denied.

AFFIRMATIVE DEFENSES

Glenmark Ltd. sets forth the following affirmative and other defenses. In doing so, Glenmark Ltd. does not intend to, and therefore does not, assume the burden of proof with respect to those related matters that, pursuant to law, Schering bears the burden.

First Affirmative Defense

27. The manufacture, importation, offer of sale, and sale of the Glenmark Ezetimibe Product as contemplated by ANDA 78-560 will not infringe, either willfully or

otherwise, nor will it contribute to the infringement of, or actively induce others to infringe, the '721 patent.

Second Affirmative Defense

28. The '721 patent is invalid for double patenting and / or failure to comply with one or more of the provisions of the Patent Statute, 35 U.S.C. § 1 *et. seq*., including but not limited to 35 U.S.C. §§ 102, 103, 112, 116, and 256.

Third Affirmative Defense

29. Plaintiffs are estopped and / or precluded from asserting that any Proposed Ezetimibe Product as indicated in ANDA 78-560 infringes or will infringe the '721 patent by reason of actions taken and statements made by the applicants of that patent to the United States Patent and Trademark Office ("PTO") during prosecution of the application(s) which led to the patent.

Fourth Affirmative Defense
Inequitable Conduct; Violation of the PTO Duty of Disclosure (37 C.F.R. ¶ 1.56)

30. The '721 patent is unenforceable due to Schering's inequitable conduct and violation of the PTO Duty of Disclosure under 37 C.F.R. ¶ 1.56 (hereinafter "Rule 56") in procuring the '721 patent from the PTO.

The '048 PCT

31. On information and belief, on July 21, 1992 Schering filed International Patent Application No. PCT/US92/05972 titled "Substituted Beta-Lactam Compounds Useful as Hypocholesterolemic Agents and Processes for the Preparation Thereof."

32. The named co-inventors of PCT/US92/05972 are Duane A. Burnett, John W. Clader, Tiruvettipuram K. Thiruvengadam, Chou-Hong Tann, and Junning Lee. At

least two of these individuals, Duane A. Burnett and John W. Clader, are also named as co-inventors of the '721 patent.

33. PCT/US92/05972 published on February 4, 1993 as International Patent Publication No. WO 93/02048 (the "'048 PCT"). This publication date was before the filing date of the '721 patent and its priority applications.

34. The '048 PCT is prior art to the '721 patent.

35. Example 9 of the '048 PCT describes a compound called 3(R)-[(3-phenylpropyl)]-1,4(S)-bis-(4-methoxyphenyl)-2-azetidinone.

36. In subsequent publications Schering has taken to calling the compound in the preceding paragraph of this Answer as "SCH48461," and that name will be used in this Answer for convenience.

37. The '048 PCT states that the compounds described in the '048 PCT, which includes SCH48461, are useful as hypocholesterolemic agents and for the treatment and prevention of atherosclerosis in mammals, including humans.

38. The '048 PCT describes experimental assays to measure the activity, both *in vitro* and *in vivo*, of its compounds.

39. The *in vitro* assay described in the '048 PCT measures the compounds' inhibition of the enzyme acyl CoA:cholesterol acyl transferase ("ACAT") from rat liver microsomes.

40. The *in vivo* assay described in the '048 PCT measures the compounds' cholesterol lowering activity when administered to hamsters on a controlled cholesterol diet.

41. The ‘048 PCT presents data from tests of its preferred compounds using both of the assays described in the preceding paragraphs of this Answer.

42. These data include data from tests of the compound SCH48461 using both the *in vitro* and the *in vivo* assay described in the ‘048 PCT.

43. By at least February 4, 1993, the prior art to the ‘048 PCT described the compound SCH48461 and its administration to mammals, including humans, to treat and prevent atherosclerosis.

44. The same prior art mentioned in the preceding paragraph of this Answer also described actual experiments in which the compound SCH48461 was administered to hamsters, and was exposed to rat microsomal proteins.

45. The ‘721 patent’s named co-inventors, Duane A. Burnett and John W. Clader, were also named co-inventors of the ‘048 PCT.

46. On information and belief, Duane A. Burnett and John W. Clader, as well as other persons and entities unknown to Glenmark Ltd. (but including Schering) who were and / or are subject to the provisions of Rule 56 relative to the filing and / or PTO prosecution of the ‘721 patent, or relative to any patent application within the family of the ‘721 patent, e.g., 37 C.F.R. ¶¶ 1.56(c), (d) (“other Schering individuals subject to Rule 56”), knew or should have known during at least the PTO prosecution of the ‘721 patent (“the ‘721 patent prosecution”) of the ‘048 PCT, as well as of the teachings of the ‘048 PCT.

47. On information and belief, Duane A Burnett and John W. Clader, as well as other Schering individuals subject to Rule 56, knew or should have known during the ‘721 patent prosecution that the ‘048 PCT was prior art to the ‘721 patent.

48. Schering filed the application that published as the ‘048 PCT.

49. On information and belief, Schering knew or should have known during the ‘721 patent prosecution of the ‘048 PCT, (i) the teachings of the ‘048 PCT, and (ii) that the ‘048 PCT was prior art to the ‘721 patent.

The Van Heek Publication

50. On information and belief, Schering and other Schering individuals subject to Rule 56 continued to investigate the compound SCH48461 after its discovery.

51. On information and belief, the investigation(s) discussed in the preceding paragraph of this Answer included experiments to isolate and characterize metabolites of the compound SCH48461.

52. On information and belief, on or about February 13, 1997 Schering and other Schering individuals subject to Rule 56 submitted a manuscript to *The Journal of Pharmacology and Experimental Therapeutics*.

53. On information and belief, the manuscript included results and other information from at least some experiments that Schering and other Schering individuals subject to Rule 56 performed to isolate and characterize metabolites of SCH48461.

54. On information and belief, the manuscript was accepted for publication by *The Journal of Pharmacology and Experimental Therapeutics* on or about June 30, 1997.

55. On information and belief, the manuscript was published in the October 1997 issue of *The Journal of Pharmacology and Experimental Therapeutics* (Volume 283, No. 1), at pages 157-163.

56. On information and belief, the manuscript was titled "*In Vivo* Metabolism-Based Discovery of a Potent Cholesterol Absorption Inhibitor, SCH58235, in the Rat and Rhesus Monkey through the Identification of the Active Metabolites of SCH48461."

57. The co-authors of the manuscript were Margaret Van Heek, Constance F. France, Douglas S. Compton, Robbie L. McLeod, Nathan P. Yumibe, Kevin B. Alton, Edmund J. Sybertz, and Harry R. Davis, Jr. For convenience, the manuscript is referred to in this Answer as the "Van Heek publication," after its first co-author Margaret Van Heek.

58. The Van Heek publication states that "[p]revious experiments determined that no intact SCH48461 … could be found in the bile of bile duct-cannulated rats that had been given an intraduodenal dose of SCH48461 and that the bile contained several different metabolites of SCH48461."

59. The Van Heek publication states further that experimental data "suggest[ ] a mechanism by which the metabolite bile might be more active than SCH48461 in inhibiting cholesterol absorption."

60. The Van Heek publication states further that "[t]o determine whether one or all of the metabolites found in the rat bile were responsible for the inhibitory activity, a pooled volume of metabolite bile was processed by a combination of solid-phase extraction, preparative RP-HPLC, and TLC."

61. According to the Van Heek publication, "[t]he biliary extract was subjected to preparative RP-HPLC … which resulted in the separation of several radioactive fractions." These fractions were said to comprise "glucuronide-conjugated metabolites."

62. The Van Heek publication states further that some of the separated fractions (fractions 2 to 6, as well as pooled material from fractions 8 and 9) were tested for cholesterol absorption inhibitory activity.

63. According to the Van Heek publication, there was insufficient material to test the remaining fractions.

64. The Van Heek publication states further that the separated fraction which had the greatest inhibitory activity, fraction 6, was further purified by TLC and subjected to mass spectral analysis.

65. The Van Heek publication states further that "[a]nother sample from this purified isolate was incubated (37°C) for 16 hr with bovine β-glucuronidase" and the resulting hydrolysate analyzed by HPLC. The findings were further corroborated by LC / MS.

66. The Van Heek publication states further that the most active SCH48461 metabolite is a glucuronidase conjugate of a compound that the Van Heek publication calls SCH53695, the chemical structure of which is shown in Figure 1, page 159, of the Van Heek publication.

67. The Van Heek publication describes an experiment that measured the cholesterol lowering activity of SCH48461 and SCH58235 when those compounds are administered to cholesterol-fed rhesus monkeys.

68. The Van Heek publication describes experiments performed by Schering and other Schering individuals subject to Rule 56 showing that the compound SCH48461, when administered to rats, is metabolized into several metabolites, and

showing also that these SCH48461 metabolites have cholesterol lowering activity in mammals.

69. The metabolites of SCH48461 described in the Van Heek publication were inherently produced when SCH48461 was administered to hamsters, as described in the '048 PCT.

70. The metabolites of SCH48461 described in the Van Heek publication were inherently produced when SCH48461 was treated with rat microsome proteins, as described in the '048 PCT.

71. The metabolites of SCH48461 described in the Van Heek publication were inherently produced when SCH48461 was administered to mammals, including humans, as described in the '048 PCT.

72. The Van Heek publication states that all of its co-authors were affiliated with "Schering-Plough Research Institute, Kenilworth, New Jersey."

73. On information and belief, Schering and other Schering individuals subject to Rule 56, knew or should have known during the '721 patent prosecution of the Van Heek publication.

74. On information and belief, Schering and other Schering individuals subject to Rule 56, knew or should have known during the '721 patent prosecution of the teachings of the Van Heek publication.

75. On information and belief, Schering and other Schering individuals subject to Rule 56, knew or should have known during the '721 patent prosecution that the metabolites of SCH48461 described in the Van Heek publication were inherently

76. On information and belief, Schering and other Schering individuals subject to Rule 56, knew or should have known during the '721 patent prosecution that the metabolites of SCH48461 described in the Van Heek publication were inherently produced when SCH48461 was treated with rat microsomal proteins, as described in the '048 PCT.

77. On information and belief, Schering and other Schering individuals subject to Rule 56, knew or should have known during the '721 patent prosecution that the metabolites of SCH48461 described in the Van Heek publication were inherently produced when SCH48461 was administered to mammals, including humans, as described in the '048 PCT.

The Clader Publication

78. On information and belief, Schering and other Schering individuals subject to Rule 56 continued work isolating and characterizing metabolites of the SCH48461 compound, and identified other metabolites in addition to the metabolite described in the Van Heek publication.

79. On information and belief, Schering and other Schering individuals subject to Rule 56 identified work isolating and characterizing other metabolites in addition to the SCH58235 metabolite described in the Van Heek publication.

80. On information and belief, one or more of the '721 patent inventors, including the named inventor John W. Clader, were aware, knew, or should have known

during the '721 patent prosecution, of the work and information described in the preceding two paragraphs of this Answer.

81. On information and belief, Schering and other Schering individuals subject to Rule 56 were aware, knew, or should have known during the '721 patent prosecution, of the work and information described in the two paragraphs preceding the previous paragraph of this Answer.

82. Ezetimibe is the active ingredient in Schering's drug product Zetia®, Schering's trade name of the drug product at issue in this litigation.

83. On information and belief, John W. Clader wrote a review article summarizing the medicinal chemistry of azetidinone cholesterol absorption inhibitors as a class, with emphasis on factors that contributed to the discovery of ezetimibe.

84. The review article by John W. Clader mentioned in the preceding paragraph of this Answer was published in the April 2005 issue of the journal *Current Topics in Medicinal Chemistry* (Volume 5, Number 3), at pages 243-256, and is titled "Ezetimibe and other Azetidinone Cholesterol Absorption Inhibitors."

85. John W. Clader, who is a named co-inventor of the '721 patent, is the only named author of the review article mentioned in the previous paragraph of this Answer. For convenience, this review article is referred to in this Answer as the "Clader publication."

86. The Clader publication states that "this review will summarize the medicinal chemistry of the azetidinone cholesterol absorption inhibitors as a class, with emphasis on factors that contributed both to the discovery of ezetimibe as well as to our overall understanding of S.A.R. [structure-activity relationship] trends in this area."

87. According to the Clader publication "[t]he discovery of SCH48461 by Burnett *et al.* remains one of the seminal events in the development of the azetidinone cholesterol absorption inhibitors."

88. The Clader publication cites to and discusses the Van Heek publication.

89. The Clader publication states that "studies by Van Heek *et al.* indicated that phenol 18 [4(S)-(4-hydroxyphenyl)-3(R)-(3-phenylpropyl)-1-(4-methoxyphenyl)-2-azetidinone] or its glucuronide is the predominant metabolite and likely the active form of SCH48461."

90. The Clader publication states further that "[a] number of other metabolites [of SCH48461] were identified in the same study" by Van Heek *et al.* of Schering.

91. The chemical structures of at least some of the "other metabolites" of SCH48461 are depicted in Figure 6, page 248, of the Clader publication.

92. The chemical compounds described in the Clader publication are each identified by a unique "compound number."

93. The "other metabolites" shown in Figure 6 of the Clader publication are identified by compound numbers 54-59.

94. At least two of the "other metabolites" of the SCH48461 compound, Compound Nos. 57a and 58 in the Clader publication, are within the scope of one or more of the claims of the '721 patent.

95. At least two of the "other metabolites" of the SCH48461 compound, Compound Nos. 57a and 58 in the Clader publication, include all claim limitations and features of at least one of the claims of the '721 patent.

96. Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was administered to hamsters, as described in the '048 PCT

97. Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was treated with rat microsomal proteins, as described in the '048 PCT.

98. Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was administered to mammals, including humans, as described in the '048 PCT.

99. On information and belief, John W. Clader, the author of the Clader publication, knew or should have known during the '721 patent prosecution that Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was administered to hamsters, as described in the '048 PCT.

100. On information and belief, John W. Clader, the author of the Clader publication, knew or should have known during the '721 patent prosecution that Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was treated with rat microsomal proteins, as described in the '048 PCT.

101. On information and belief, John W. Clader, the author of the Clader publication, knew or should have known during the '721 patent prosecution that Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was administered to mammals, including humans, as described in the '048 PCT.

102. On information and belief, Schering and other Schering individuals subject to Rule 56 knew or should have known during the '721 patent prosecution that

Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was administered to hamsters, as described in the '048 PCT.

103. On information and belief, Schering and other Schering individuals subject to Rule 56 knew or should have known during the '721 patent prosecution that Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was treated with rat microsomal proteins, as described in the '048 PCT.

104. On information and belief, Schering and other Schering individuals subject to Rule 56 knew or should have known during the '721 patent prosecution that Compound Nos. 57a and 58 in the Clader publication were inherently produced when SCH48461 was administered to mammals, including humans, as described in the '048 PCT.

105. On information and belief, John W. Clader, the author of the Clader publication and a named co-inventor of the '721 patent, knew or should have known during the '721 patent prosecution that Compound Nos. 57a and 58 in the Clader publication are within the scope of one or more of the claims of the '721 patent.

106. On information and belief, John W. Clader, the author of the Clader publication and a named co-inventor of the '721 patent, knew or should have known during the '721 patent prosecution that Compound Nos. 57a and 58 in the Clader publication include all claim limitations and features of at least one of the claims of the '721 patent.

Additional Schering Publications

107. On information and belief, Margaret Van Heek, Douglas S. Compton, Constance F. France, Robert L. McLeod, Nathan P. Yumibe, Kevin B. Alton and Harry

R. Davis, Jr. submitted an abstract entitled "Isolation and Identification of the Active Metabolite(s) of SCH48461 and Possible in vivo Mechanism of Action for their Inhibition of Cholesterol Absorption" ("the van Heek Abstract") to the XII International Symposium on Drugs Affecting Lipid Metabolism, Nov. 7-10, 1995, Westin Galleria and Westin. Oaks Hotel, Houston, Texas, USA, which was published in the meeting's book of abstracts.

108. The Van Heek Abstract reports that SCH48461 rat bile is more potent than SCH48461 and states "[t]he metabolites in bile were separated by HPLC; fractions were tested … to assess cholesterol absorption inhibition. The most active fraction was identified by mass spectrometry as the C4-phenol of SCH48461. The other fractions had moderate or no activity."

109. On information and belief, Harry R. Davis, Jr., Margaret van Heek, Robert W. Watkins, Stuart B. Rosenblum, Douglas S. Compton, Lizbeth M. Hoos, Daniel G. McGregor, Katherine Pula and Edmund J. Sybertz submitted an abstract entitled "The Hypocholesterolemic Activity of the Potent Cholesterol Absorption Inhibitor SCH 58235 Alone and in Combination with HMG CoA Reductase Inhibitors" ("the Davis Abstract") to the XII International Symposium on Drugs Affecting Lipid Metabolism, Nov. 7-10, 1995, Westin Galleria and Westin. Oaks Hotel, Houston, Texas, USA, which was published in the meeting's book of abstracts.

110. The Davis Abstract states "[ezetimibe] was discovered through the identification of the active biliary metabolites of SCH48461 and extensive structure activity relationship information."

111. On information and belief, Stuart B. Rosenblum, Tram N. T. Huynh, Harry R. Davis, Jr., Nathan P. Yumibe, John W. Clader, Adriano Afonso and Duane A. Burnett submitted an abstract entitled "Discovery of SCH 58235. A Potent Orally Active Inhibitor of Cholesterol Absorption" ("the Rosenblum Abstract") to the XII International Symposium on Drugs Affecting Lipid Metabolism, Nov. 7-10, 1995, Westin Galleria and Westin. Oaks Hotel, Houston, Texas, USA, which was published in the meeting's book of abstracts.

112. The Rosenblum Abstract states "[t]he potential sites of metabolism of SCH 48461 were considered, the most likely metabolites were prepared (12 analogs), and many were confirmed as present in vivo . . . Based on analysis of the metabolite structure-activity relationship, it was determined that benzylic oxidation of the C3-propyl side chain is advantageous."

113. On information and belief, Sundeep Dugar, Nathan P. Yumibe, John W. Clader, Monica Vizziano, Keith Huie, Margaret Van Heek, Douglas S. Compton and Harry R. Davis, Jr. submitted a manuscript to Bioorganic & Medicinal Chemistry Letters ("the Dugar Paper") entitled "Metabolism and Structure Activity Data Based Drug Design: Discovery of (-) SCH 53079 and Analog of the Potent Cholesterol Absorption Inhibitor (-) SCH 48461", which was published in the November 1996 issue (Volume 6, No. 11), at pages 1271-1274.

114. The Dugar paper states "[m]etabolism studies indicated that there were four primary sites of metabolism for (-)SCH 48461, (Figure 1), with metabolites resulting from demethylation, hydroxylation and/or oxidation and combinations thereof, resulting in the formation of eleven metabolites." Figure 1 of the Dugar Paper contains an arrow

originating from the word "hydroxylation" and pointing to the benzylic position of a chemical structure depicting (-)SCH 48461.

PTO Duty of Disclosure – The '751 Application

115. On March 18, 1996, Schering, through its attorney Anita W. Magatti, filed patent application No. 08/617,751 ("the '751 application").

116. The '751 application issued on June 16, 1998 as U.S. Patent No. 5,767,115 ("the '115 patent").

117. When filing the '751 application, Schering and Magatti also submitted an Information Disclosure Statement to the PTO "listing the publications known to [the '751] applicants which may be relevant to [the '751] application."

118. The "publications" listed in the Information Disclosure Statement included the '048 PCT.

119. In a letter accompanying the Information Disclosure Statement, Schering and Magatti stated that the '048 PCT "provide[s] additional background information on cholesterol biosynthesis inhibitors and β-lactam cholesterol absorption inhibitors."

120. Throughout the prosecution of the '751 application, Magatti never disclosed the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract or the Dugar Publication to the PTO in any Information Disclosure Statement or other paper she filed for the '751 application.

121. Throughout the prosecution of the '751 application, Magatti never disclosed the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract or the Dugar Publication to the PTO.

122. Throughout the prosecution of the '751 application, neither Schering nor other Schering individuals subject to Rule 56 disclosed the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract or the Dugar Publication to the PTO in any Information Disclosure Statement or other papers filed for the '751 application.

123. Throughout the prosecution of the '751 application, neither Schering nor other Schering individuals subject to Rule 56 disclosed the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract or the Dugar Publication to the PTO.

124. On information and belief, neither Magatti, Schering, nor other Schering individuals subject to Rule 56 ever informed any PTO Patent Examiner that any compounds described, recited, or claimed in the '751 application were metabolites of the SCH48461 compound described in the '048 PCT.

125. On information and belief, neither Magatti, Schering, nor other Schering individuals subject to Rule 56 ever informed any PTO Patent Examiner that these metabolites were inherently produced when SCH48461 was administered to humans, treated with rat microsomal proteins, or administered to mammals (including humans), as described in the '048 PCT.

126. When filing and during prosecution of the '751 application, Magatti, Schering, and other Schering individuals subject to Rule 56 had an uncompromising duty of candor and good faith in dealing with PTO, which included the duty to disclose to the PTO information known to them to be material to patentability.

127. When filing and during prosecution of the '751 application, Magatti, Schering, and other Schering individuals subject to Rule 56 had an uncompromising duty of candor and good faith in dealing with PTO, which included the duty to disclose to

the PTO information which should have been known to them to be material to patentability.

128. On information and belief, in preparing and filing the '751 application and its Information Disclosure Statement, and throughout the prosecution of the '751 application, Magatti conferred with or obtained information from one or more of the '721 patent inventors and / or other Schering individuals subject to Rule 56 in accordance with her Duty of Disclosure before the PTO.

129. On information and belief, in preparing and filing the '751 application and its Information Disclosure Statement, and throughout the prosecution of the '751 application, Schering and other Schering individuals subject to Rule 56 conferred with or obtained information from one or more of the '721 patent inventors in accordance with their Duty of Disclosure before the PTO.

130. The persons with whom Magatti, Schering, and / or other Schering individuals subject to Rule 56 conferred, or from they obtained information, had an uncompromising duty of candor and good faith to disclose to the PTO information known to them to be material to patentability of the '751 application.

131. On information and belief and as discussed in detail earlier in this Answer, the failure of either Magatti, Schering, and / or other Schering individuals subject to Rule 56, to disclose the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract or the Dugar Publication and the studies and other information described in those publications to the PTO during prosecution of the '751 application, was an intentional and knowing act.

132. On information and belief and as discussed in detail earlier in this Answer, the failure of either Magatti, Schering, and / or other Schering individuals subject to Rule 56, to disclose to the PTO during prosecution of the '751 application that the metabolites of the SCH48461 compound were within the scope of one or more claims of the '751 application, was an intentional and knowing act.

133. On information and belief and as discussed in detail earlier in this Answer, the failure of either Magatti, Schering, and / or other Schering individuals subject to Rule 56, to disclose to the PTO during prosecution of the '751 application that the metabolites of the SCH48461 compound were inherently produced when SCH48461 was administered to humans, as described in the '048 PCT, was an intentional and knowing act.

134. On information and belief and as discussed in detail earlier in this Answer, the failure of either Magatti, Schering, and / or other Schering individuals subject to Rule 56, to disclose to the PTO during prosecution of the '751 application that the metabolites of the SCH48461 compound were inherently produced when SCH48461 was treated with rat microsomal proteins, as described in the '048 PCT, was an intentional and knowing act.

135. On information and belief and as discussed in detail earlier in this Answer, the failure of either Magatti, Schering, and / or other Schering individuals subject to Rule 56, to disclose to the PTO during prosecution of the '751 application that the metabolites of the SCH48461 compound were inherently produced when SCH48461 was administered to mammals (including humans), as described in the '048 PCT, was an intentional and knowing act.

136. The information in paragraph 120 of the Answer is material to the patentability of the '751 application.

137. The information in paragraph 120 of the Answer is more material to the patentability of the '751 application than the information before the PTO Patent Examiner during the prosecution of that application.

138. The information in paragraph 121 of the Answer is material to the patentability of the '751 application.

139. The information in paragraph 121 of the Answer is more material to the patentability of the '751 application than the information before the PTO Patent Examiner during the prosecution of that application.

140. The information in paragraph 122 of the Answer is material to the patentability of the '751 application.

141. The information in paragraph 122 of the Answer is more material to the patentability of the '751 application than the information before the PTO Patent Examiner during the prosecution of that application.

142. The information in paragraph 123 of the Answer is material to the patentability of the '751 application.

143. The information in paragraph 123 of the Answer is more material to the patentability of the '751 application than the information before the PTO Patent Examiner during the prosecution of that application.

144. The information in paragraph 124 of the Answer is material to the patentability of the '751 application.

145. The information in paragraph 124 of the Answer is more material to the patentability of the '751 application than the information before the PTO Patent Examiner during the prosecution of that application.

146. The information in paragraph 125 of the Answer is material to the patentability of the '751 application.

147. The information in paragraph 125 of the Answer is more material to the patentability of the '751 application than the information before the PTO Patent Examiner during the prosecution of that application.

148. On information and belief, Magatti, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '751 application that the information in paragraph 120 of the Answer was material and / or more material to the patentability of the '751 application than other information before the PTO Patent Examiner during the prosecution of that application.

149. On information and belief, Magatti, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '751 application that the information in paragraph 121 of the Answer was material and / or more material to the patentability of the '751 application than other information before the PTO Patent Examiner during the prosecution of that application.

150. On information and belief, Magatti, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '751 application that the information in paragraph 122 of the Answer was material and / or more material to the patentability of the '751 application than other information before the PTO Patent Examiner during the prosecution of that application.

151. On information and belief, Magatti, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '751 application that the information in paragraph 123 of the Answer was material and / or more material to the patentability of the '751 application than other information before the PTO Patent Examiner during the prosecution of that application.

152. On information and belief, Magatti, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '751 application that the information in paragraph 124 of the Answer was material and / or more material to the patentability of the '751 application than other information before the PTO Patent Examiner during the prosecution of that application.

153. On information and belief, Magatti, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '751 application that the information in paragraph 125 of the Answer was material and / or more material to the patentability of the '751 application than other information before the PTO Patent Examiner during the prosecution of that application.

154. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 120 of the Answer important in deciding whether to allow the '751 application to issue as a patent.

155. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 121 of the Answer important in deciding whether to allow the '751 application to issue as a patent.

156. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 122 of the Answer important in deciding whether to allow the '751 application to issue as a patent.

157. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 123 of the Answer important in deciding whether to allow the '751 application to issue as a patent.

158. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 124 of the Answer important in deciding whether to allow the '751 application to issue as a patent.

159. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 125 of the Answer important in deciding whether to allow the '751 application to issue as a patent.

160. On information and belief, Schering's and Magatti's intentional withholding from the PTO of the information in paragraph 120 of the Answer was done with an intent to deceive and / or mislead the PTO.

161. On information and belief, Schering's and Magatti's intentional withholding from the PTO of the information in paragraph 121 of the Answer was done with an intent to deceive and / or mislead the PTO.

162. On information and belief, Schering's and Magatti's intentional withholding from the PTO of the information in paragraph 122 of the Answer was done with an intent to deceive and / or mislead the PTO.

163. On information and belief, Schering's and Magatti's intentional withholding from the PTO of the information in paragraph 123 of the Answer was done with an intent to deceive and / or mislead the PTO.

164. On information and belief, Schering's and Magatti's intentional withholding from the PTO of the information in paragraph 124 of the Answer was done with an intent to deceive and / or mislead the PTO.

165. On information and belief, Schering's and Magatti's intentional withholding from the PTO of the information in paragraph 125 of the Answer was done with an intent to deceive and / or mislead the PTO.

166. On information and belief, Schering's and Magatti's intentional withholding of the material information in paragraph 120 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

167. On information and belief, Schering's and Magatti's intentional withholding of the material information in paragraph 121 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

168. On information and belief, Schering's and Magatti's intentional withholding of the material information in paragraph 122 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

169. On information and belief, Schering's and Magatti's intentional withholding of the material information in paragraph 123 breached their duty of candor and good

faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

170. On information and belief, Schering's and Magatti's intentional withholding of the material information in paragraph 124 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

171. On information and belief, Schering's and Magatti's intentional withholding of the material information in paragraph 125 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

PTO Duty of Disclosure – The '996 Application

172. On June 15, 2000, Schering, through its attorneys ("Schering's counsel"), filed patent application No. 09/594,996 ("the '996") for reissue of the '115 patent. The '996 application issued on May 28, 2002 as U.S. Patent No. RE37,721 -- the '721 patent.

173. When filing the '996 application, Schering's counsel also submitted an Information Disclosure Statement to the PTO listing items that "may be deemed to be pertinent to the above-identified application." The Information Disclosure Statement was signed by one of Schering's counsel.

174. The items listed in the Information Disclosure Statement that accompanied the '996 application included the '048 PCT.

175. On June 13, 2001, Schering's counsel submitted a second Information Disclosure Statement for the '996 application. That second Information Disclosure Statement was signed by another of Schering's counsel.

176. Neither Schering, other Schering individuals subject to Rule 56, or Schering's counsel listed the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract or the Dugar Publication in either Information Disclosure Statement submitted for the '996 application.

177. Throughout the prosecution of the '996 application, neither Schering, other Schering individuals subject to Rule 56, nor Schering's counsel disclosed the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract or the Dugar Publication to the PTO.

178. On information and belief, neither Schering, other Schering individuals subject to Rule 56, nor Schering's counsel ever informed any PTO Patent Examiner that any compounds described, recited, or claimed in the '996 application were metabolites of the SCH48461 compound described in the '048 PCT.

179. On information and belief, neither Schering, other Schering individuals subject to Rule 56, nor Schering's counsel ever informed any PTO Patent Examiner that these metabolites were inherently produced when SCH48461 was administered to humans, metabolized by rat microsome enzymes, and administered to mammals (including humans), as described in the '048 PCT.

180. When filing and during prosecution of the '996 application, Schering, other Schering individuals subject to Rule 56, and Schering's counsel had an

uncompromising duty of candor and good faith in dealing with PTO, which included the duty to disclose to the PTO information known to them to be material to patentability.

181. When filing and during prosecution of the '996 application, Schering, other Schering individuals subject to Rule 56, and Schering's counsel had an uncompromising duty of candor and good faith in dealing with PTO, which included the duty to disclose to the PTO information which should have been known to them to be material to patentability.

182. On information and belief, in preparing and filing the '996 application and its Information Disclosure Statements, and throughout the prosecution of the '996 application, Magatti and Schering's counsel conferred with or obtained information from one or more of the '721 patent inventors and / or other Schering individuals subject to Rule 56 in accordance with their Duty of Disclosure before the PTO.

183. On information and belief, in preparing and filing the '996 application and its Information Disclosure Statements, and throughout the prosecution of the '996 application, Schering and other Schering individuals subject to Rule 56 conferred with or obtained information from one or more of the '721 patent inventors in accordance with the Duty of Disclosure before the PTO.

184. The persons with whom Schering's counsel, Schering, and / or other Schering individuals subject to Rule 56 conferred, or from whom they obtained information, had an uncompromising duty of candor and good faith to disclose to the PTO information known to them to be material to patentability of the '996 application.

185. On information and belief and as discussed in detail earlier in this Answer, the failure of either Schering's counsel, Schering, and / or other Schering individuals

subject to Rule 56, to disclose the Van Heek publication, Davis Abstract, Rosenblum Abstract, Van Heek Abstract, Dugar Publication and the studies and other information described in those publications to the PTO during prosecution of the '996 application, was an intentional and knowing act.

186. On information and belief and as discussed in detail earlier in this Answer, the failure of either Schering's counsel, Schering, and / or other Schering individuals subject to Rule 56, to disclose to the PTO during prosecution of the '996 application that the metabolites of the SCH48461 compound were within the scope of one or more claims of the '996 application, was an intentional and knowing act.

187. On information and belief and as discussed in detail earlier in this Answer, the failure of either Schering's counsel, Schering, and / or other Schering individuals subject to Rule 56, to disclose to the PTO during prosecution of the '996 application that the metabolites of the SCH48461 compound were inherently produced when SCH48461 was administered to humans, as described in the '048 PCT, was an intentional and knowing act.

188. On information and belief and as discussed in detail earlier in this Answer, the failure of either Schering's counsel, Schering, and / or other Schering individuals subject to Rule 56, to disclose to the PTO during prosecution of the '996 application that the metabolites of the SCH48461 compound were inherently produced when SCH48461 was treated with rat microsomal proteins, as described in the '048 PCT, was an intentional and knowing act.

189. On information and belief and as discussed in detail earlier in this Answer, the failure of either Schering's counsel, Schering, and / or other Schering individuals

subject to Rule 56, to disclose to the PTO during prosecution of the ’996 application that the metabolites of the SCH48461 compound were inherently produced when SCH48461 was administered to mammals (including humans), as described in the ‘048 PCT, was an intentional and knowing act.

190. The information in paragraph 176 of the Answer is material to the patentability of the ‘996 application.

191. The information in paragraph 176 of the Answer is more material to the patentability of the ‘996 application than the information before the PTO Patent Examiner during the prosecution of that application.

192. The information in paragraph 177 of the Answer is material to the patentability of the ‘996 application.

193. The information in paragraph 177 of the Answer is more material to the patentability of the ‘996 application than the information before the PTO Patent Examiner during the prosecution of that application.

194. The information in paragraph 178 of the Answer is material to the patentability of the ‘996 application.

195. The information in paragraph 178 of the Answer is more material to the patentability of the ‘996 application than the information before the PTO Patent Examiner during the prosecution of that application.

196. The information in paragraph 179 of the Answer is material to the patentability of the ‘751 application.

197. The information in paragraph 179 of the Answer is more material to the patentability of the '751 application than the information before the PTO Patent Examiner during the prosecution of that application.

198. On information and belief, Schering's counsel, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '996 application that the information in paragraph 176 of the Answer was material and / or more material to the patentability of the '996 application than other information before the PTO Patent Examiner during the prosecution of that application.

199. On information and belief, Schering's counsel, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '996 application that the information in paragraph 177 of the Answer was material and / or more material to the patentability of the '996 application than other information before the PTO Patent Examiner during the prosecution of that application.

200. On information and belief, Schering's counsel, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '996 application that the information in paragraph 178 of the Answer was material and / or more material to the patentability of the '996 application than other information before the PTO Patent Examiner during the prosecution of that application.

201. On information and belief, Schering's counsel, Schering, and other Schering individuals subject to Rule 56 knew or should have known during the prosecution of the '996 application that the information in paragraph 179 of the Answer was material and / or more material to the patentability of the '996 application than other information before the PTO Patent Examiner during the prosecution of that application.

202. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 176 of the Answer important in deciding whether to allow the '996 application to issue as a patent.

203. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 177 of the Answer important in deciding whether to allow the '996 application to issue as a patent.

204. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 178 of the Answer important in deciding whether to allow the '996 application to issue as a patent.

205. There was a substantial likelihood that a reasonable examiner would have considered the information in paragraph 179 of the Answer important in deciding whether to allow the '996 application to issue as a patent.

206. On information and belief, Schering's and Schering's counsel's intentional withholding from the PTO of the information in paragraph 176 of the Answer was done with an intent to deceive and / or mislead the PTO.

207. On information and belief, Schering's and Schering's counsel's intentional withholding from the PTO of the information in paragraph 177 of the Answer was done with an intent to deceive and / or mislead the PTO.

208. On information and belief, Schering's and Schering's counsel's intentional withholding from the PTO of the information in paragraph 178 of the Answer was done with an intent to deceive and / or mislead the PTO.

209. On information and belief, Schering's and Schering's counsel's intentional withholding from the PTO of the information in paragraph 179 of the Answer was done with an intent to deceive and / or mislead the PTO.

210. On information and belief, Schering's and Schering's counsel's intentional withholding of the material information in paragraph 176 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

211. On information and belief, Schering's and Schering's counsel's intentional withholding of the material information in paragraph 177 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

212. On information and belief, Schering's and Schering's counsel's ntentional withholding of the material information in paragraph 178 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

213. On information and belief, Schering's and Schering's counsel's intentional withholding of the material information in paragraph 179 breached their duty of candor and good faith in dealing with the PTO, and their duty to disclose to the PTO information known to them to be material to patentability.

Fifth Affirmative Defense

214. Glenmark Ltd. incorporates by reference the allegations of paragraphs 27 through 213 as if fully set forth herein.

215. Plaintiffs' claims are barred by the doctrine of unclean hands.

Sixth Affirmative Defense

216. Glenmark Ltd. incorporates by reference the allegations of paragraphs 27 through 215 as if fully set forth herein.

217. The patent term extension (PTE) to the '721 patent is invalid for failure to comply with one or more of the provisions of the Patent Statute including, but not limited to, 35 U.S.C. § 156, or the Patent Rules, 37 C.F.R. § 1.710 *et seq.*

Seventh Affirmative Defense
Inequitable Conduct; Violation of the PTO Duty of Disclosure (37 C.F.R. ¶ 1.765)

218. Glenmark Ltd. incorporates by reference the allegations of paragraphs 27 through 217 as if fully set forth herein.

219. On December 17, 2002, Schering, through its attorney, filed with the PTO an application for a patent term extension for the '721 patent based on the regulatory approval of NDA #21-445 for ezetimibe. The PTO issued a certificate of patent term extension of 497 days on August 23, 2006.

220. During the extended period (i.e., the period between the original expiration date of the '721 patent, June 16, 2015, and the expiration date with the PTE, October 25, 2016), the rights derived from the patent are limited to certain uses for ezetimibe, salts thereof, and esters thereof. Ezetimibe, salts of ezetimibe, and certain esters of ezetimibe are within the scope of claims 1, 2, 5, and 7.

221. During the pendency of the PTE application, Schering's counsel, Schering, other Schering individuals subject to 37 C.F.R. §1.765 (hereinafter "Rule 765"), and/or other persons and entities who were subject to the provisions of Rule 765 relative to the PTE proceeding knew or should have known that claims 1, 2, 5, and 7 of

the '721 Patent were invalid due to inherent anticipation, and that this information is at least pertinent to the rights that would be derived from the PTE.

222. Throughout the PTE proceeding, neither Schering nor other Schering individuals subject to Rule 765 disclosed to the PTO that claims 1, 2, 5, and 7 of the '721 Patent were invalid.

223. The information in paragraph 222 was material information adverse to a determination of entitlement to the PTE sought.

224. Due to Schering's inequitable conduct and violation of the PTO Duty of Disclosure under Rule 765 in procuring the PTE from the PTO, the entire '721 Patent is rendered unenforceable.

225. Due to Schering's inequitable conduct and violation of the PTO Duty of Disclosure Rule 765 in procuring the PTE from the PTO, the '721 patent is rendered unenforceable during the 497 day PTE.

COUNTERCLAIMS

INTRODUCTION

226. Defendant / Counterclaim Plaintiff Glenmark Pharmaceuticals, Ltd. ("Glenmark Ltd."), hereby counterclaims against Plaintiff / Counterclaim Defendant Schering Corporation ("Schering"), as follows:

227. Glenmark Ltd. brings these Counterclaims against Schering under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

228. Glenmark Ltd.'s Counterclaim recites causes of action arising under the Patent Laws of the United States, Title 35 U.S.C. §§ 1 *et seq*., and are based on a continuing and justiciable case or actual controversy between Glenmark Ltd. and

Schering with respect to the non-infringement, invalidity, and / or unenforceability of United States Patent No. RE 37,721 ("the '721 patent"), as evidenced by Schering's assertion of its claims in its First Amended Complaint.

THE PARTIES

229. Glenmark Pharmaceuticals Ltd. is an Indian corporation having a place of business at Glenmark House, HDO-Corporate Building, Wing-A, B.D. Sawant Marg., Chakala, Off Western Express Highway, Andheri [East], Mumbai 400 099, India.

230. Upon information and belief, Schering is a corporation duly organized and existing under the laws of the State of New Jersey, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, N.J. 07033-0530.

231. Upon information and belief, MSP Singapore Company, LLC ("MSP") is a corporation organized and existing under the law of the state of Delaware, having a principal place of business at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033.

THE PATENT-IN-SUIT

232. The '721 patent is titled "Hydroxy-substituted azetidinone compounds useful as hypocholesterolemic agents" and is purportedly owned by Schering.

JURISDICTION AND VENUE

233. This Court has subject matter jurisdiction over these Counterclaims under 28 U.S.C. § 1331, 28 U.S.C. § 1338(a), and 28 U.S.C. §§ 2201 *et seq*. as declaratory judgment actions for patent non-infringement, patent invalidity, and / or patent unenforceability, arising under the Patent Laws of the United States, 35 U.S.C. §§ 1 et seq.

234. This Court has *in personam* jurisdiction over Schering and MSP because, *inter alia*, Schering and MSP have subjected themselves to the jurisdiction of this Court for purposes of these Counterclaims.

235. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c) and 28 U.S.C. § 1400(b).

COUNTERCLAIM 1
(Declaratory Judgment of Invalidity of the '721 Patent)

236. Glenmark Ltd. incorporates the allegations of paragraphs 27 through 235 above as if fully set forth in this paragraph.

237. An actual and justiciable case or controversy exists between Glenmark Ltd. and both Schering and MSP as to validity of the '721 patent.

238. On October 25, 2006, Abbreviated New Drug Application ("ANDA") 78-560 was filed with the U.S. Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355(j). ANDA 78-560 seeks FDA approval to market 10 milligram ezetimibe tablets ("the Glenmark Ezetimibe Product").

239. One or more claims of the '721 patent are invalid for double patenting and / or failure to meet one or more of the requirements of patentability set forth in the Patent Statute, *inter alia*, 35 U.S.C. §§ 101, 102, 103, 112, 116, and 256.

COUNTERCLAIM 2
(Declaratory Judgment of Unenforceability of the '721 Patent)

240. Glenmark Ltd. incorporates the allegations of paragraphs 27 through 239 above as if fully set forth in this paragraph.

241. An actual and justiciable case or controversy exists between Glenmark Ltd. and both Schering and MSP as to enforceability of the '721 patent.

242. The '721 patent, and all patents in the '721 family of patents, are unenforceable for inequitable conduct before the PTO by Schering, other Schering individuals subject to Rule 56, and Schering's counsel, and / or failure on the part of Schering, other Schering individuals subject to Rule 56, and Schering's counsel, to comply with the PTO Duty of Disclosure under Rule 56.

COUNTERCLAIM 3
(Declaratory Judgment of Invalidity of the Patent Term Extension for the '721 Patent)

243. Glenmark Ltd. incorporates the allegations of paragraphs 27 through 242 above as if fully set forth in this paragraph.

244. An actual and justiciable case or controversy exists between Glenmark Ltd. and both Schering and MSP as to validity of the PTE granted pursuant to 35 U.S.C. §156 for the '721 patent.

245. The PTE granted by the PTO is invalid for failure to meet one or more of the requirements set forth in the Patent Statute, *inter alia*, 35 U.S.C. § 156.

COUNTERCLAIM 4
(Declaratory Judgment of Unenforceability of the '721 Patent during the Patent Term Extension Period)

246. Glenmark Ltd. incorporates the allegations of paragraphs 27 through 245 above as if fully set forth in this paragraph.

247. An actual and justiciable case or controversy exists between Glenmark Ltd. and both Schering and MSP as to enforceability of the '721 patent during the period of patent term extension pursuant to 35 U.S.C. §156.

248. The '721 patent is entirely unenforceable, and at the very least unenforceable during the period of patent term extension, for inequitable conduct before the PTO by Schering, other Schering individuals subject to Rule 56, and Schering's

counsel, and / or failure on the part of Schering, other Schering individuals subject to Rule 56, and Schering's counsel, to comply with the PTO Duty of Disclosure under Rule 765.

*** * * ***

249. The actions and assertions made by Schering that Glenmark Ltd. is infringing the '721 patent have caused and will continue to cause irreparable injury to Glenmark Ltd.

PRAYER FOR RELIEF

WHEREFORE, Glenmark Ltd. prays for relief as follows:

A. That the plaintiffs / counterclaim defendants take nothing by their action and the First Amended Complaint be dismissed with prejudice;

B. That the Court enter a declaratory judgment that the '721 patent is invalid;

C. That the Court enter a declaratory judgment that the '721 patent is unenforceable;

D. That the Court find that this is an exceptional case and award to Glenmark Ltd. its attorneys' fees in this action under 35 U.S.C. § 285;

E. That the Court award Glenmark Ltd. its costs and expenses; and

F. That the Court grant Glenmark Ltd. such other relief as this Court may deem just and proper.

Pursuant to Fed. R. Civ. P. 38(b), Defendants / Counterclaim Plaintiffs demand a trial by jury on all issues triable of right, or operation of law, by jury.

Dated: March 10, 2008

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